DOCKET NO.: A0848.70004US00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Silence et al.

Serial No.:

10/534,292

Confirmation No.:

1144

Filed:

May 9, 2005

For:

CAMELIDAE ANTIBODIES AGAINST

IMMUNOGLOBULIN E AND USE THEREOF FOR THE

TREATMENT OF ALLERGIC DISORDERS

Examiner:

Michael Szperka

Art Unit:

1644

## Certificate of Mailing Under 37 CFR 1.8(a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 28, 2008

Signature

(Michelle M. Quinn)

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is responsive to the restriction requirement mailed September 28, 2007.

In order to comply with the requirement to elect one of the inventions set forth by the Examiner, Applicant hereby elects Group 1 – Claims 15 and 16 – drawn to methods of administering single domain antibodies that bind TNF $\alpha$ , with traverse. Claims 15 and 16 read on the elected invention, along with linking claims 1-8. It is Applicant's understanding that the restriction requirement will be withdrawn upon the allowability of the linking claims and that claims depending from the linking claims (or including limitations thereof) will be rejoined and examined.

Applicant's election is made without prejudice to pursuing other inventions in additional applications.

Applicant respectfully traverses the restriction requirement. The invention described and claimed in the above-identified patent application is based on the finding that certain anti-target therapeutic polypeptides (i.e. polypeptide constructs comprising one or more single domain antibodies) can be delivered to a subject by a non-invasive route (i.e. not parenterally/by injection) without being inactivated. This general inventive concept is reflected in claims 1-8 (which are indicated by the Examiner as linking claims). Applicant notes that the Examiner indicates that, upon allowance of these linking claims, the restriction requirement as to the linked inventions would be withdrawn.

Applicant provides the following additional reasons for traversal of the restriction requirement.

As noted above, a first inventive concept is the non-invasive delivery of therapeutic polypeptides (i.e. polypeptide constructs comprising one or more single domain antibodies). Therefore Applicant proposes that claims related to the inventive concept of non-invasive delivery of the therapeutic polypeptides (independent of the target of the therapeutic polypeptide) should be joined (claims 1-8, 15-27, 46, 52-53, and new claims 64-67, which are provided in the accompanying preliminary amendment). Accordingly, it is proposed that Groups 1, 2, 3, 4, 5, 6, 7, 8, 9 as identified by the Examiner can be considered as one invention. Applicant notes that this inventive concept is quite similar to the grouping of claims based on the linking claims as identified by the Examiner. Applicant respectfully requests election of this inventive concept.

To clarify the nature of this first inventive concept, Applicant has filed herewith a preliminary amendment of the claims that amends claim 1 to refer to oral administration of the polypeptide constructs. As the inventive concept applies to *oral administration*, claims 1, 2, 8, 15-27, 46, 52, 53 and 64-67 as amended in the accompanying preliminary amendment.

Another inventive concept is the delivery of therapeutic polypeptides inside cells by use of a single domain antibody against an internalizing receptor. Claims relating to this second

inventive concept are claims 28-46. Accordingly, it is proposed that Groups 11-22 and 24 as identified by the Examiner can be considered as one invention.

Claim 46 (which presently is allocated to Group 10) relates to both inventive concepts described above and can therefore be allocated to both of the foregoing inventive concepts.

Another inventive concept relates to single domain antibodies against a certain target, such as IgE. Therefore, claims relating to single domain antibodies against IgE could be joined as well (claims 54-60 and 62-63). Accordingly, it is proposed that Groups 9 and 23 as identified by the Examiner can be considered as one invention.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check or credit card payment, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By:

John R. Van Amsterdam, Ph.D.

Reg. No. 40,212

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: A0848.70004US00

Date: February 28, 2008

X02/28/08x